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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,881	10/31/2003	Thomas R. Skwarek	P-11670.00	2004

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,881	SKWAREK ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "51" has been used to designate both implantable drug pump and drug delivery catheter in Figure 5, and because reference characters "94" and "51" have both been used to designate drug delivery catheter (paragraph [56]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: there is a typographical error in paragraph [40] reading "monnopolar," which should be corrected to read –monopolar--. In paragraph [55], the typographical error "system 53" should be corrected to read –system 50--. In paragraph [59], the typographical error "over the coarse of time" should be corrected to read –over the course of time--.

Appropriate correction is required.

4. Claim 24 is objected to because of the following informalities: there is a typographical error which reads "a pulse generator generate" which should be corrected to read –a pulse generator **to** generate--. Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3, 5-11, 18, 24, 26, 30, 32, and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-11, 14-16, 22-28, 33-37, 40, 53, 56-58, 61-62, 65-67, 70-73, 78-82, 85-89, and 99-102 of copending Application No. 10/441,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications disclose a method and device with one or more leads for the delivery of one or more therapeutic stimulation pulses or sequences to tissue via an implantable medical device for the purpose of treating sexual dysfunction, where the stimuli might

be delivered in response to telemetry signals from a patient programmer or in response to a sensed physiological signal, and might also be delivered in conjunction with a drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5-10, 14, 17-18, 24-27, 28-32, and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Krakovsky et al. (US Patent 5,454,840).

Regarding claims 1-3, 5-10, 14, and 18, Krakovsky et al. discloses a method of delivering one or more therapeutic stimulation pulses to the prostate (Fig. 11) via an implantable medical device (potency package 30) to treat sexual dysfunction in which the stimulation can cause an erection and either cause (Fig. 13) or prevent (Fig. 12) ejaculation (column 1, lines 42-53) or premature ejaculation (column 5, lines 32-33). The stimulation may be delivered in response to telemetry signals from a patient programmer (column 1, lines 36-38, 44-45). The second pulse train includes more

pulses per unit time (is of higher frequency) than the first pulse train (Figs. 12-13). The disclosed method can also comprise delivering drugs to the prostate in conjunction with delivering electrical stimulation pulses (column 4, lines 28-54).

Regarding claims 24-32 and 38-39, Krakovsky et al. discloses an implantable medical device (potency package 30) comprising one or more leads (Fig. 10, leads 48 and 49), a pulse generator (46), an optional agent pump (the implantable drug pump consisting of chamber 60, pump 62, and delivery tube 64) and a processor (42) to control the therapy delivery circuit; wherein the second pulse train includes more pulses per unit time than the first pulse train (Figs. 12 and 13); wherein the device defines pulses with amplitudes less than 10.5 volts and frequencies between 2 and 20 Hz, and is capable of pulse widths between 10 and 500 microseconds and pulse intervals of 10 to 500 milliseconds (Fig. 12, column 3, lines 36-46); wherein the device is capable of causing the fiber structure of the prostate gland to relax, given these programmed parameters.

It is noted that claim 28 and, by way of dependency, claim 29 invoke the means-plus-function language of 35 U.S.C. 12, 6th paragraph, where the means for generating and delivering a training sequence of stimulation pulses is taken to refer to the device described above comprising one or more leads, one or more pulse generators, and a processor control circuit.

It is noted that the functional language of the device claims does not distinguish the instant application over the Krakovsky et al. device because the earlier patented device is inherently capable of all the limitations contained in the instant claims.

9. Claims 1-3, 5-12, 14-20 and 22-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitehurst et al. (US Patent 6,901,294, hereinafter referred to as Whitehurst'294).

Regarding claims 1-3 and 5-12, 14-20, 22-23, and 33-37, Whitehurst'294 discloses a method of delivering one or more therapeutic stimulation pulses (electrical or drug) directly to the prostate gland via an implantable medical device controlled by user input (column 10, lines 56-65) or response to sensed physiological events (column 11, lines 35-59) for the treatment of sexual dysfunction and cause erection, additionally either causing or preventing ejaculation. (column 3, line 54 through column 4, line 33; column 10, lines 56-65).

Regarding claims 24-32 and 38-39, Whitehurst'294 discloses an implantable device comprising one or more leads, a pulse generator and a processor for delivery of electrical or drug stimulation pulses to the tissue of the prostate (abstract; column 4, lines 11-33)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 4, 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky et al. or Whitehurst'294 in view of Whitehurst et al. (US Patent 6,885,895, hereafter referred to as Whitehurst'895) and Mann et al. (US Patent 6,941,171).

Krakovsky et al. and Whitehurst'294 disclose the method of the instant application substantially as claimed except for the parameter limitations of using pulse widths between 180 and 450 microseconds and frequencies between 50 and 100 Hz (claim 4) or 2 and 20 Hz (claim 11). Whitehurst'895 teaches a frequency range of 50-100 Hz as being likely to produce the desired control and response of male sexual function, with the low end of the range being excitatory (causing erection and ejaculation) and the high end of the range being inhibitory (preventing ejaculation or premature ejaculation) (column 17, lines 34-56). Mann et al. teaches a pulse width range of 50-350 microseconds and a frequency range of 2-20 pulses per second (Hz) as being typical for electrical stimulation of male reproductive nerves (column 21, line 48 through column 22, line 14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ these ranges for stimulation parameters in the method of the Krakovsky et al. or Whitehurst'294 patents to achieve the same advantage of successful and clinically safe control of male sexual function (motivation to combine provided by Whitehurst'895, column 17, lines 34-56; and Mann et al., column 21, line 48 through column 22, line 14).

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky et al. in view of Whitehurst'294.

Krakovsky et al. discloses the method of the instant application substantially as claimed except that the therapeutic stimulation pulses may be delivered in response to a sensed physiological condition. Whitehurst'294 teaches sensing necrosis, volume or inflammation of tissue as well as hormone, enzyme, or drug levels and changes as a means to determine the strength, duration, and pattern of electrical stimulation required to produce the desired treatment effect (column 11, lines 35-59).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a sensor for sensing physiological conditions into the device and method of the Krakovsky et al. patent for the same advantage of an alternate or more accurate means for determining the proper therapy levels to be delivered to the patient (motivation to combine provided by Krakovsky et al., column 11, lines 35-59).

14. Claims 12, 15-16, 19-23 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky et al. in view of Mann et al.

Krakovsky et al. discloses the method of the instant application substantially as claimed except that the therapeutic stimulation pulses be used to train the prostate gland to become more compliant, i.e. relax its fiber structure. Mann et al. teaches a stimulation of the nerve pathways of the bladder that yields the desired result of diminishing involuntary bladder contractions (i.e. relaxing the fibrous muscle structure of the bladder) and increasing volume of the bladder (i.e. increasing compliance of the bladder wall).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that similar stimulation of the prostate, given its similar physical composition to the bladder and its corollary position in the reproductive system to that of the bladder in the urinary system, could be employed in the method of the Krakovsky et al. patent to achieve the same results of a relaxing of the fiber structure and increase in compliance of the prostate organ.

See Figs. 12 and 13 of Krakovsky et al. regarding claims 34-37.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

George Manuel
Primary Examiner